FEB 2 2 2001

Analytic
SYBRON DENTAL SPECIALTIES

K003640

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
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Colleen Boswell - Contact Person

Date Summary Prepared: November 2000

Device Name:
- Trade Name - MiniEndo III
- Common Name - Ultrasonic Generator
- Classification Name - Ultrasonic Scaler, per 21 CFR § 872.4850

Devices for Which Substantial Equivalence is Claimed:
- Satelec, *Suprasson P5 Booster*

Device Description:
The device is an is an AC-powered, ultrasonic generator consisting of a main control unit, handpiece and foot pedal, intended to be used in dentistry for scaling and endodontic treatment. The handpiece is connected to the control unit via a fixed electrical cable connection. The tips are mounted at the end of the handpiece by means of a tip wrench. All Mini-Endo III tips vibrate in a single plane (vibration from front to rear and along the tip axis) via piezoelectric ultrasonic power. The straight motion allows a more accurate and more comfortable approach to the tooth and gingiva. The Mini-Endo III operates from the action of cavitation following the propagation of ultrasounds in a frequency spectrum between 28 and 35 kHz and a mechanical effect following vibration of the tips mixing with water within a range of maximum amplitudes varying from 5 to 250 μm. The handpiece is autoclavable.

The main control unit includes all control and ultrasonic power generation functions. The power settings can be varied from 1 to 10 depending upon the clinical application. Internal electronics generate electrical signals at the ultrasound frequency in order for the tip at the end of the handpiece to vibrate. Irrigation is provided by a water line manually controlled by a spray adjust knob which adjusts the spray at the tip of the handpiece and is located on the front of the control unit.

The foot pedal has two functions. Pressure on the pedal activates/deactivates the piezoelectric ultrasonic vibration and enables/disables the flow switch inside the main control unit for irrigation.

Intended Use of the Device:
The intended use of the MiniEndo III is to provide piezoelectric ultrasonic vibration for scaling and endodontic treatment.

Substantial Equivalence:
The MiniEndo III is substantially equivalent to several other legally marketed devices in the United States. The MiniEndo III functions in a manner similar to and is intended for the same use as the Suprasson P5 Booster marketed by Satelec.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2001

Ms. Colleen Boswell
Director of Corporate Compliance
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K003640
Trade Name: Miniendo III
Regulatory Class: II
Product Code: ELB
Dated: November 21, 2000
Received: November 27, 2001

Dear Ms. Boswell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K003640

510(k) Number (if known): K003640

Device Name: MiniEndo III

Indications For Use:

The MiniEndo III is an AC-powered, ultrasonic generator consisting of a main control unit, handpiece and foot pedal, intended to be used in dentistry for scaling and endodontic treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003640